



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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Memorandum

Subject: EFED Response to USDA/APHIS' "Partner Review Comments: Preliminary Analysis of Rodenticide Bait Use and Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: A Comparative Approach (June 9, 2004)"

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Through: Tom Bailey, Branch Chief
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Attached are EFED's comments on APHIS' review of the comparative rodenticide risk assessment dated June 9, 2004. We have inserted EFED's response after each APHIS comment that pertains to the comparative risk assessment (comment 6 relates to BEAD's benefits assessment). Some of these issues were addressed in EFED's response to registrants' comments during the 30-day "errors-only" comment period in 2001 and comments submitted during the 120-day "public-comments" period from January to May of 2003. The present submission also includes a copy of APHIS' comments from March 31, 2003, and they request that comments 2, 4, 5, 6, 7, 8, and 9 be addressed. EFED addressed those comments in our July 17, 2004 "Response to Public Comments on EFED's Risk Assessment: *"Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach"*, dated December 19, 2002", and we reiterate our response to those comments as well. We have also attached a table of many zinc phosphide use sites, methods of application, application rates and number of

applications permitted, although many product labels do not provide that information. A list of the names of more than 70 target species also is included.

APHIS' comments and EFED's response to those comments are provided below. The full text of APHIS' comments are in the EDocket.

APHIS comments dated August 4, 2004:

- 1) APHIS would like to reiterate a serious concern regarding both the previous and the current drafts of the document we reviewed. This document is not, as stated, "an assessment of potential risk". This draft successfully addresses the hazard aspect of risk. However, the exposure component of risk is not adequately considered. No attempt has been made to address the exposure scenarios that necessarily include application methods, timing, rates, etc. This, therefore, is not a risk assessment. Presumably EPA's overall goal is to mitigate potential risk to non-target birds and mammals. Hazard or toxicity of a chemical is constant. It is only by addressing exposure that risk can be mitigated. Thus exposure cannot be ignored.

EFED Response to Comment 1: The exposure profile component of the revised risk assessment uses the best available data and a lines-of-evidence approach. Baits can be formulated with whole grains (wheat, barley, oats, corn, milo, millets), grain-based pellets, fruits (grapes, mulberry, apples, pears, apricots, figs), nuts, sunflower seeds, vegetables (carrots, sweet potato, potato, cabbage), fresh vegetation (alfalfa, dandelions, beet tops), and meat-based products (ground meat, canned or dry meat-based cat or dog foods). Many of these foods are likely to be highly attractive to granivorous, frugivorous, omnivorous, and even carnivorous birds and mammals. Zinc phosphide is registered for controlling more than 70 mammalian species, mostly a variety of rodents, but also lagomorphs (jackrabbits) and insectivores (moles). Zinc phosphide baits are applied (often by multiple aerial, ground-machine (e.g., cyclone spreader), or hand broadcasts) to a wide variety of treatment sites, ranging from in and around buildings to rangeland and pastures, rights-of-way, orchards and groves, vineyards, uncultivated areas, croplands, waterways, lawns and golf courses, nurseries, ornamentals, forestry, and numerous other sites. A list of treatment sites, application methods, bait formulations, and target species is attached. It should be noted that for many uses, both for commensal and field uses, product labels do not specify either an application rate (lb/acre) nor put any limitations on the number of applications that can be made, other than a few uses with seasonal restrictions. Repeat applications are likely to increase the likelihood of exposure of nontarget organisms.

The issue of quantifying exposure is addressed in the revised comparative risk assessment and in EFED's *Reponse to Public Comments* dated July 17, 2004 and is worth repeating here:

EFED's risk assessment is in accord with the Agency's Guidelines for Ecological Risk Assessment [Guidelines for Ecological Risk Assessment. EPA/630/R-95/002F, April 1998, Final. 171 pp. <http://www.epa.gov/ncea/ecorsk.htm>]. Registrants are correct in noting that the Guidelines state that "*Ecological risk assessment is a process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure*

to one or more stressors"(PART A, page 1, paragraph 1). However, the Guidelines go on to state that *"Descriptions of the likelihood of adverse effects may range from qualitative judgments to quantitative probabilities. Although risk assessments may include quantitative risk estimates, quantitation of risks is not always possible. It is better to convey conclusions (and associated uncertainties) qualitatively than to ignore them because they are not easily understood or estimated"* (PART A, page 1, paragraph 3). Refining the exposure assessment to establish a quantitative measure of likelihood of exposure and effects would require a much more extensive data set than registrants have submitted for their rodenticides and for the nontarget species potentially at risk. The Agency provided the preliminary risk assessment to rodenticide registrants in October, 2001 and posted it in the EDocket on EPA's website for public comments from January 29 to May 30, 2003. No additional data or relevant information to refine the exposure assessment has been provided by the registrants or other stakeholders. The necessary data have been outlined in a section on *"Uncertainty and Data Needs"* in the refined assessment. Nevertheless, despite the lack of quantifiable data, the existence of substantial incident data along with liver-residue analysis confirms that birds and nontarget mammals are being exposed and adversely affected by applications of rodenticide baits. The fact that numerous species of birds and mammals, including predators and scavengers, have been found exposed to these baits indicates that both primary and secondary exposures are occurring.

EFED's risk conclusions are based on analyses of the available data by a "lines-of-evidence" approach and comparative-analysis modeling. Quantitative estimates of risk are used in both; however, the "lines-of evidence" assessment includes qualitative assessments of secondary risk based on mortality and other adverse effects reported in laboratory and field studies, operational control programs, and incident reports, as well as toxicokinetic data and residue levels reported in primary consumers. This approach is in concert with the Guidelines, which clearly state that professional judgement or other qualitative evaluation techniques are appropriate for ranking risks using categories such as low, medium, and high when exposure and effects data are limited or are not easily expressed in quantitative terms. A "lines-of-evidence" approach also has been advocated by the Avian Effects Dialogue Group for helping to interpret the variety of information collected during field studies [see Rymph, B. (ed.). 1994. *Assessing Pesticide Impacts on Birds: Final Report of the Avian Effects Dialogue Group, 1988-1993*. RESOLVE Center for Environmental Dispute Resolution, Washington, DC. 156 pp]. Regarding the lines-of-evidence analysis, one of the expert external peer reviewers stated that *"The bulk of the material in the document addresses the development of the weight of evidence argument. In general this part of the document is well-developed and it is hard to argue with the evident conclusion about each of the nine chemicals. These conclusions are largely implicit in the text since the task of deriving a formal assessment for each chemical is passed over to the decision support analysis. The case about each chemical is thoroughly and logically developed in this part of the document and the document is commendable in showing how the Agency staff have been able to develop the weight of evidence approach as a viable approach to the synthesis of a complex body of evidence."* The three expert peer reviews are available in the Rodenticide Cluster

EDocket, www.epa.gov/oppsrrd1/rodenticidecluster/index.htm]

EFED also notes that the methodology used is similar to that used in the Agency's "Comparative Analysis of Acute Risk From Granular Pesticides" (EPA 1992) and "A Comparative Analysis of Ecological Risks from Pesticides and Their Use: Background, Methodology, Case Study" (EPA 1998); both were reviewed by a FIFRA Scientific Review Panel. Concerning the latter analysis, the Panel noted the many scientific uncertainties in the method, yet agreed that it was a useful screening tool that provides a rough estimate of relative risk. The Panel made a number of helpful suggestions to improve the utility of the method, most of which are included in the risk assessment.

- 2) EPA's Section 7 consultation with the U.S. Fish and Wildlife Service (FWS) is a beneficial addition. The FWS has not only identified those threatened and endangered species that may be impacted, but also included recommendations for mitigation of potential adverse effects. The mitigation measures are in the form of buffer zones that prevent or reduce possible exposure.

EFED Response to Comment 2: OPP's Endangered Species Protection Program will be addressing endangered species issues and, if necessary, reinitiating consultation with the U. S. Fish and Wildlife Service for the nine rodenticides addressed in their 1993 Biological Opinion [USFWS Biological Opinion: Effects of 16 Vertebrate Control Agents On Threatened and Endangered Species. March, 1993. 168 pp.]

- 3) The inclusion of all available incident data is appropriate for a discussion of risk. However, EPA has not adequately discussed the new data provided by the American Society for the Prevention of Cruelty to Animals (ASPCA) Poison Control Center. The text assumes the poisonings are a result of rodenticide application. Does the ASPCA track the mechanism of exposure in their database? The incidents may be due to exposure during normal labeled use, poisoning from accidental ingestion of stored rodenticides, or from the too common problem of intentional and illegal poisoning of dogs and other canines. We suggest EPA review their agency enforcement data to evaluate the severity of illegal canine poisoning using pesticides. EPA appears again to be ignoring the exposure aspect of risk. If the exposure data are not available, which is often the case in other poison control center databases, EPA needs to acknowledge the lack of data.

EFED Response to Comment 3: EFED does not conduct risk assessments for pets and domestic animals. Those issues are addressed by OPP's Health Effects Division, and they likely would be willing to accept any relevant data that APHIS could provide. ASPCA did provide EFED with the number of incidents reported in their database during an 18-month period. Mostly these were incidents with dogs. Because there is a substantial cost in

obtaining the individual incident reports, EFED could not obtain them, nor has any registrant provided them to EFED. However, the fact that there were more than 2300 incidents reported for rodenticides indicates that dogs and other pets are being exposed to rodenticide baits. Whether this exposure is due to intentional or inadvertent misuse or improper storage is unclear, but a combination of these means of exposure seems likely. Possibly label warnings and application directions are not adequate to prevent exposure. That is an issue that can be addressed during the mitigation phase.

We do note that at least one of APHIS' zinc phosphide products (EPA Registration No. 56228-6 - Zinc Phosphide Concentrate "*For the control of voles, house mice, white-footed mice, norway rats, roof rats, polynesian rats, rice rats, Florida water rats, cotton rats, pocket gophers, muskrats, nutria, prairie dogs, wood rats, ground squirrels, marmots and woodchucks, and black-tailed jackrabbits . . .*") states that "*Dogs, cats and other nontarget animals may actively search for bait, especially when meat-based baits are used.*" Thus, it would seem inappropriate to imply that all exposure of dogs is due to intentional misuse or improper storage of baits. We also note other warnings on the labels of zinc phosphide baits. For example, EPA Reg. No. 56228-6 is a Restricted Use Pesticide "*Due to hazards to nontarget species*", which implies that nontarget animals might be exposed to baits. This and other labels also state that "*This product is toxic to wildlife and fish. Birds and other wildlife feeding in treated areas may be killed.*" Labels also have a section entitled "*Endangered Species Considerations*" that requires applicators to determine if endangered species are present in the treatment area. We assume that this warning relates to bait application in the field, not solely to misuse or storage situations. That APHIS includes such warnings and precautions on their product labels indicates that they are indeed aware that there is a potential risk to nontarget organisms.

- 4) The current comparative risk model can provide some useful information. However, there are several characteristics of zinc phosphide which demonstrate that assumptions in the model need to be adjusted:
 - a) The model may not be as useful for comparison of pesticides having different mechanisms of action, particularly if that mechanism influences the quantity of active ingredient consumed, which translates to different levels of exposure. Zinc phosphide, once ingested, produces phosphine gas (the toxic agent) in the stomach. This mechanism is rapid (hours) compared to anti-coagulants (days). Generally rodents will continue to consume anti-coagulants for several days, whereas rodents will quickly stop consuming bait treated with zinc phosphide in part due to rapid onset of toxicosis. In addition, zinc phosphide has a disagreeable taste leading to bait shyness. In either case, the relatively high concentration of a rodenticide in bait is not equivalent to exposure, because animals do not consume equal amounts of bait. These differences in exposure are not incorporated into the model.

EFED Response to Comment 4a: EFED agrees that the amount of bait eaten over a several-day period does have consequences for risk. For example, second-generation anticoagulants can provide a lethal dose to a primary consumer in a single feeding, but death is delayed and the animal may continue feeding and accumulating residue for several or more days. In contrast, zinc phosphide kills quickly. Because residues do not accumulate to any significant extent in consumers of zinc phosphide bait, EFED made a presumption of minimal secondary risks to avian and mammalian predators and scavengers. That presumption is supported by studies in which poisoned rodents have been fed to avian and mammalian predators and/or scavengers and observed for adverse effects. However, for primary consumers, the issue is not the total quantity of bait that might be eaten but rather if the amount of bait that might be eaten will provide a lethal dose or have other adverse effects (e.g., reproductive). Zinc phosphide grain baits are formulated mostly at 2% ai (1% for fruits, nuts, vegetables and 3% for meats), versus the 0.005% ai baits for the second-generation anticoagulants. Because they are formulated at such higher concentrations of active ingredient, very little bait needs to be eaten to provide an LD50 dose. As tabulated in the comparative risk assessment (see Table 28 in the revised assessment), a 25-g bird needs to eat only about 0.02 g of a 2% ai zinc phosphide bait to ingest an LD50 dose, and that accounts for only about 0.3% of the amount of food it will eat in a day. Because a bird is likely to eat a pellet or treated grain whole, rather than chewing it, it will ingest multiple LD50 doses. A small mammal might chew only a piece of a pellet or grain, but a 25-g nontarget mammal needs to eat only about 0.03 g of bait to ingest an LD50 dose (see Table 31). Even if bait shyness is a factor, an animal is likely to consume multiple LD50 doses before avoiding any additional bait. As already noted, zinc phosphide baits are targeted for control of more than 70 mammalian species, and APHIS has provided no data demonstrating that baits are selective to these target species and won't be eaten by nontarget species. [see also EDED Response to Comment 4c]

- b) Another indication that the model may need an adjustment is that the model results are inconsistent with EPA's own incident data for zinc phosphide. The EIIS data suggest that birds may be at far greater risk than mammals, as indicated by the relative number of animals in each class reported in the database. But the model predicts the exact opposite. There are many times more incidents and numbers of birds than mammals in the data. As with the ASPCA data (as it is reported in the risk document), the EIIS data may not reflect exposure. In addition, reporting may be incomplete and not indicative of actual incidents. For example, small mammals may be in burrows and not visible. However, the observation that the model and the incident data do not support each other should raise questions.

EFED Response to Comment 4b: There are no inconsistencies between the incident database and EFED's risk conclusions, but we agree with APHIS that the incidents do indicate that birds that eat zinc phosphide baits are at risk. The incident database is not comprehensive and contains only incidents that have been reported to the Agency (see section entitled

“Incident Data: Birds and Nontarget Mammals” in the comparative risk assessment). The fact that there are more bird incidents than mammal incidents is not surprising. Larger birds such as geese, ducks, and wild turkeys are much more likely to be found, analyzed, and reported to local, state, or federal authorities than are small mammals. As APHIS notes, small mammals may die in burrows (or other hiding places such as crevices and dense vegetation) where they would be inconspicuous and easily overlooked. The fact that they are not represented in the incident database is not surprising, but it does not mean they are not at risk.

- c) There is also inconsistency between the model results for zinc phosphide and EPA’s own concern regarding the efficacy of the USDA registered products. EPA has conducted label reviews of 2% zinc phosphide bait products. In the most recent review (April 5, 2004) EPA expressed concern about mediocre performance. Bait shyness by rodents is an issue with zinc phosphide. Again, this relates to exposure. If the exposure is relatively low, the corresponding risk is low. And again, the model predicts high risk to mammals.

EFED Response to Comment 4c: Agency efficacy-testing guidelines require that 70% control must be achieved in field tests and 90% mortality obtained in laboratory tests. Many zinc phosphide products have met those standards and are currently registered. However, it is inappropriate to compare efficacy against target species to risks to nontarget species. Efficacy would be mediocre if only 60% or 65% of the target species were killed in a field trial. Yet, 60 or 65% mortality of one or more nontarget species could be devastating to that species.

- 5) USDA/APHIS provided a number of comments on the December 19, 2002 draft in a letter to EPA dated March 31, 2003. The majority of these comments have not yet been addressed. A copy of the March 31, 2003 letter is attached for your reference. Please direct your attention to comments numbered 2, 4, 5, 6, 7, 8 and 9.

EFED Response to Comment 5: Responses to Public Comments will be issued when the revised comparative risk assessment and BEAD’s benefits assessment are issued. APHIS’ comments are addressed in that response. However, we will respond to APHIS’ comments 2, 4, 5, 6, 7, 8, and 9 as requested (see below).

Synopsis of APHIS comments from March 31, 2003:

Comment 2: APHIS agrees that technical materials can be toxic to birds and mammals but argues that end-use products offer some degree of selectivity due their unique formulations and application directions. *“End-use products are formulated with many different carriers, strengths and can be applied under a wide range of use patterns and methods (Broadcast, underground, bait stations, indoors, outdoors, etc.). These factors afford some level of selectivity for primary risk. These factors should be considered and assessed prior to imposing mitigation measures.”* APHIS goes on to state that *“The development of zinc phosphide into effective products included the use of many different grains, stickers, flavors, stabilizers, dyes, etc. Today, manufacturers have settled on a few formulations. These formulations have been selected because of the high degree of acceptance by target species, but also because they present less hazard to nontarget species than other formulations.”* APHIS adds that a submission by Eisemann et al. (1999) entitled *“A literature review (1942-1998): Efficacy of zinc phosphide for controlling Norway rats, roof rats, house mice, Peromyscus sp., prairie dog, and ground squirrels”* (MRID No. 449066-01) has been submitted to the Agency, and it included a hard copy of 103 manuscripts that reinforces the point that site-specific risk assessments should be performed prior to imposing any mitigation measures.

EFED Response to Comment 2: APHIS has provided no information that anything in product formulations deters nontarget species or is highly specific to the target species. The label for Zinc Phosphide Concentrate (EPA Registration No. 56228-6) provides mixing instructions for a variety of baits. Meat-based baits are made solely with a meat base (ground meat, canned dog or cat food, or dry meat-based pet food) mixed with zinc phosphide concentrate. Sunflower-seed baits are made by mixing sunflower seeds, zinc phosphide concentrate, and mineral oil. Fruit and vegetable baits are made by mixing a fruit (grapes, mulberry, apricots, figs, apples, pears), nut (unspecified), vegetable (carrots, sweet potato, potato, cabbage), or vegetation (alfalfa, dandelions, beet tops) with zinc phosphide concentrate and vegetable oil. Granted, not all nontarget species will eat meat or vegetables, but they are likely to be attractive to many species. Adding vegetable oil might actually enhance their attractiveness to some nontarget species.

Regarding application methods, EFED recognizes that there are many application methods (see EFED attachment). Some methods, such as underground baiting for pocket gophers and moles, likely does minimize exposure of surface-feeding birds and mammals. However, the suggestion that broadcasting bait by aircraft, ground-driven machines, or by hand is selective to the target species is not supported by any data and seems highly improbable; in fact, broadcasting seems a highly unselective method of applying bait. Many of the aerial broadcast application rates are higher than those for ground broadcast (machine or by hand) or when hand baited. That higher rate would seem to suggest that aerial broadcast may, in fact, be less selective.

APHIS is inconsistent in comments about the efficacy of zinc phosphide baits. In the

comment above APHIS states that “*These formulations have been selected because of the high degree of acceptance by target species*”, yet in their comments of June 9, 2004 state that “*EPA has conducted label reviews of 2% zinc phosphide bait products. In the most recent review (April 5, 2004) EPA expressed concern about mediocre performance.*” How does a high degree of acceptance by target species lead to mediocre performance?

APHIS’ submission submitted under MRID No. 449066-01 is an efficacy submission. Efficacy studies are reviewed by OPP’s Registration Division. Such studies conducted with the target species, under Agency efficacy testing guidelines, and they are not adverse-effects studies. That efficacy submission referred to contains 103 documents encompassing more than 1600 pages. If APHIS believes that there is any relevant information for assessing nontarget risks, the appropriate documents should be cited and brought to EFED’s attention.

Comment 4: APHIS believes that pen studies conducted by Ramey et al. (1994) and Ramey et al. (1998) are not discussed in enough detail in the comparative risk assessment.

EFED Response to Comment 4: The Ramey et al. (1994) study conducted in alfalfa enclosures does demonstrate that pheasants may eat zinc phosphide bait and that they may be killed if they do so. Quail also were present but did not eat bait. The fact that the quail presumably found alternative food suggests that pheasants could have done so as well and were not forced to eat the bait. The study does clearly indicate that birds can be killed if they eat zinc phosphide bait. That doesn’t mean that every bird in every zinc phosphide treatment site will eat bait and die, but it does suggest that under some situations some birds may eat bait and be at risk. Whether nontarget animals eat bait in any particular situation likely depends on many factors, including food preferences and the availability of alternative foods. Bait may be more readily eaten if natural foods are scarce and that can vary annually, geographically, seasonally, and even weekly and daily. Can one argue that because the quail didn’t eat bait in the alfalfa enclosure that they will never do so under any circumstance? On the other hand, because pheasants ate bait and died in the enclosures does not mean that every pheasant on every zinc phosphide treatment area will eat bait and die. However, it does suggest that some birds will eat bait and are at risk if they do so.

The Ramey et al. (1998) study was conducted with pheasants in alfalfa fields in the Sacramento Valley of California. Zinc phosphide was applied between alfalfa cuttings, at which time pheasants were not utilizing the fields. Therefore, pheasants were not exposed. Based on that study, EPA registered this use of zinc phosphide. But does this mean there is no risk to zinc phosphide? The study did not address geographical differences in pheasant behavior and diets, nor did it address any possible annual differences at the study sites. Pheasants in the highland alfalfa-growing areas in California might behave differently, and so might those in Minnesota alfalfa fields. The study also did not address risks to other species

that might have been exposed. The researchers did conduct transects across treated fields. However, searches were done using ATVs, and small birds and nontarget mammal carcasses, especially those inside burrows or dying off the fields, might have been overlooked. Therefore, while this was a well conducted study on the risks of pheasants in treated alfalfa fields in central California, there are many uncertainties in extrapolating these results to other areas and possibly even other years.

Comment 5: APHIS questions why EFED hasn't used zinc phosphide use information they provided to an EFED reviewer at a meeting in 1996.

EFED Response to Comment 5: EFED welcomes any relevant use data for zinc phosphide and the other rodenticides. The Agency provided the preliminary risk assessment to rodenticide registrants in October, 2001 and posted it in the EDocket on EPA's website for public comments from January 29 to May 30, 2003. No additional data or relevant information to refine the exposure assessment has been provided by the registrants or other stakeholders. We are not aware of the information APHIS said was provided in a handout at a meeting in 1996 - it is not in EFED's file for zinc phosphide nor does the zinc phosphide chemical reviewer have any recollection of receiving that information. However, we have tabulated current zinc phosphide uses, target species, and application methods (see attachment and responses to previous comments). This information is current, whereas information from the early 1990's may be outdated for some uses. Regarding production data, EPA does obtain data on the amount of each product produced annually. However, many zinc phosphide products have many use sites and target species on individual product labels (e.g., APHIS product 56228-6). Production data provide no information on when, where, or how the product was used and thus provide little relevant information for assessing exposure and risk.

Some of those same problems apply to the Pesticide Use Reporting by the California Department of Pesticide Regulation (<http://www.cdpr.ca.gov/docs/pur/purmain.htm>). The annual reporting only provides the amount of rodenticide applied per crop without providing any information of the target pest, seasonal use, application method (e.g., broadcast versus bait station), or other such relevant factors. Moreover, homeowners and non-certified applicators do not report pesticide use, and noncrop uses are poorly represented or lumped together.

Comment 6: Very few incidents have been reported during the past 60 years of zinc phosphide use. The Agency should compare the number of incidents with the use information discussed under Comment 5.

EFED Response to Comment 6: The fact that few incidents have been reported could be due to a variety of reasons. One is that few incidents occur. However, it could also be that incidents occur but are not detected or reported. That most reported incidents for rodenticides

involve anticoagulants is not surprising, because anticoagulants are stored in body tissues and can be detected by analyzing liver tissue. Confirmation of zinc phosphide poisoning is much more difficult, because the phosphine gas is liberated and not stored in the body. It is generally detected by the presence of dyed bait in the crop, stomach, or alimentary canal. The presence of an acetylene odor also is diagnostic of zinc phosphide toxicity but can be detected only if intact carcasses are sent to an examining laboratory soon after death (Michigan Wildlife Diseases Manual: Zinc Phosphide www.dnr.state.mi.us/wildlife/division/RoseLake). Neither the incident information nor the use information is adequate to make a comparison of the number of incidents per application or any other such criteria. EFED has addressed this issue in the “*Target species, use sites, and rodenticide usage*” section of the revised comparative risk assessment and in EFED’s July 17, 2004 “*Response to Public Comments on EFED’s Risk Assessment: “Potential Risks of Nine Rodenticides to Birds and Nontarget Mammals: a Comparative Approach”*”, dated December 19, 2002”.

Comment 7: The value of carcass searches during efficacy field studies has been undervalued. Data collected during systematic onsite searches is stronger than that collected by accidental discovery.

EFED Response to Comment 7: As noted in EFED’s Response to Comment 2, efficacy studies are designed to address effectiveness of the bait and application method in controlling the target species. Efficacy tests are not designed to assess risks to nontarget species, and they rarely do so other than occasionally searching for carcasses along transects on treatment plots. However, in terms of the impact of a bait on nontarget organisms, simply walking transects across treated areas can be misleading. As APHIS astutely pointed out in Comment 4b, “*For example, small mammals may be in burrows and not visible.*”, and small birds may fly offsite before dying. A good effects study needs to assess nontarget population levels before and after control by means such as mark-recapture or radio telemetry. APHIS argues in Comment 1 that exposure has not adequately been assessed, but how does walking transects adequately address exposure? It doesn’t and can be misleading. For example, the search efficiency of the individuals doing the transect searches must be determined but usually isn’t, nor are those individuals inside burrows accounted for. EFED has provided guidance for conducting field trials to assess nontarget exposure (Fite et al. 1988: *Guidance Document for Conducting Terrestrial Field Studies*, EPA 540/09-88-109), including design considerations, addressing search efficiency, and methods appropriate for assessing nontarget impacts. We also encourage APHIS to discuss study protocols with EFED prior to initiating a field study.

Comment 8: Prior to requiring avian production data, APHIS suggests that EFED examine chronic data collected by other OPP divisions. APHIS also cites four chronic or subchronic rat studies that were submitted to the Agency.

EFED Response to Comment 8: EFED will look at those studies to determine if there are any relevant information for mammals. EFED typically utilizes the rat two-generation reproduction test (40 CFR §158.340, Toxicology Data Requirements, Guidelines Reference No. 83-4 "Reproduction, 2-generation") to assess chronic risks to mammals. This study is required by OPP's Health Effects Division (HED) to support pesticides with food uses or where use of the product is likely to result in human exposure over a significant portion of the human lifespan. This study is not currently available for zinc phosphide or for any of the other rodenticides. Most other subchronic/chronic studies (e.g., neurotoxicity, dermal, inhalation, oncogenicity) required by HED are not relevant to assessing risk to nontarget mammals from food baits. For birds, EFED uses avian reproduction studies with the northern bobwhite and mallard (40 CFR §158.490, Wildlife and Aquatic Organisms Data Requirements, Guidelines Reference No. 71-4 "Avian reproduction"). The avian reproduction studies have previously been required by the Agency on a case-by-case basis, but the updated guideline requirements soon to be published will require these studies for all pesticides having outdoor uses. EFED can better assess the potential for adverse reproductive effects when these data become available.

Comment 9: APHIS states that rodents are hesitant to accept zinc phosphide treated grains. Baiting efficacy is greatly improved when treated sites are first prebaited with untreated grain. Aversive properties can be assumed to extend to other mammals and should be considered.

EFED Response to Comment 9: The argument that bait aversion can be reduced by prebaiting, at least for some species, may be correct and is not disputed by EFED. However, we note that nontarget mammals also would be prebaited and thus more likely to accept bait as well. Product labels recommend prebaiting for some species but not others (see attachment), suggesting that zinc phosphide treated grains may not be aversive to some species. What about birds? What about baits other than grains (meat-based baits, nuts, sunflower seeds, fruits, vegetables, vegetation)? The fact that there are at least 70 mammalian species listed as target species for zinc phosphide baits indicates that many mammals will eat bait. Moreover, as previously discussed, very little bait needs to be eaten to provide an LD50 dose to a small mammal or small bird.

Zinc Phosphide Field and In-and-Around Building Uses for Control of Rodents, Lagomorphs, and Insectivores

Many zinc phosphide baits are formulated as 2% ai grain (corn, oats, wheat, barley, rye, millet, milo) baits or grain-based pellets. Other baits include 3.25 % ai meat-based baits (ground meat, canned dog or cat food, or dry meat-based pet food), 3.25% ai sunflower-seed baits, and 1% ai baits made with fruit (grapes, mulberry, apricots, figs, apples, pears), nuts (unspecified types), vegetables (carrots, sweet potato, potato, cabbage), or fresh vegetation (alfalfa, dandelions, beet tops). A 1% ai grain bait is registered for use only in California. Prebaiting with untreated bait for 2-3 days prior to bait application is recommended, but not required, for some uses as noted in the table.

Common and scientific names of target species are listed after the table.

Note: The tabulated information is based on a review of registered zinc phosphide labels. Several labels were not available for review; thus, the information may not be complete. However, EFED believes that the majority of uses and target species have been captured in this table.

Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
<i>In and Around Buildings:</i>				
Commensal rats and mice White-footed mouse Voles	Hand Baiting and/or Bait Stations; Baits: <ul style="list-style-type: none"> • Meats (ground meat, canned or dry dog or cat food) • Grains (wheat, oats, barley, rye, milo, or millet) • Fruits (grapes, mulberry, apricots, figs, apples, pears) • Sunflower seeds • Nuts • Vegetables (carrots, sweet potato, cabbage, potato) • Greens (alfalfa, dandelions, beet tops) 	not specified	unlimited	no

Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
<i>Orchards (dormant season) and/or Groves:</i>				
White-footed mouse Voles Ground squirrels (CA)	Aerial or Ground Broadcast Machine Baiting Hand Baiting Bait Stations (includes sunflower-seed baits)	6-10 3-6 2-3 or ns not specified	unlimited	no
Ground squirrels	Ground Broadcast Hand Baiting (includes fruit and vegetable baits)	6 not specified	≥30-day int. unlimited	yes
Woodrats	Hand Baiting	not specified	unlimited	no
Cotton rat Voles Ground squirrels	Hand Baiting (CA)	not specified	unlimited	yes
Commensal rats	Hand Baiting (CA)	not specified	every 3 mo.	yes
<i>Vineyards:</i>				
White-footed mouse Voles	Aerial or Ground Broadcast Trail Builder (TB) Hand Baiting Baits: includes fruits and sunflower seeds	6-10 2-3 3-5	unlimited	no
Ground squirrels	Ground Broadcast Hand Baiting (includes fruit and vegetable baits)	6 not specified	≥30-day int.	yes
Voles Native mice	Ground Broadcast	6-10	unlimited	no
Ground squirrels	Ground Broadcast Hand Baiting (CA)	6-10	unlimited	yes

Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
Ground squirrels Voles Cotton rat	Hand Baiting (CA)	not specified	unlimited	yes
Commensal rats	Hand Baiting	not specified	every 3 mo.	yes
<i>Rangeland (including adjacent timber areas in MT and WY):</i>				
Ground squirrels	Hand Baiting	not specified	unlimited	yes
Ground squirrels	Aerial or Ground Broadcast Hand Baiting (CA)	6-10 not specified	1 1	yes
Voles	Aerial or Ground Broadcast (CA)	6	1	yes
Voles White-footed mouse	Aerial or Ground Broadcast Trail Builder Hand Baiting	6-10 not specified not specified	unlimited	no
	Trail Builder Hand Baiting	2-3 3-5	unlimited	no
Woodrats Kangaroo rats	Hand Baiting	not specified	unlimited	no
Woodchuck Marmot Black-tailed jackrabbit	Hand baiting	not specified	unlimited	yes
Moles Pocket gophers	Burrow Builder	2-3	unlimited	no
Commensal rats	Hand Baiting (CA)	not specified	every 3 mo.	yes

Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
<i>Rangeland and Pastures in ND, SD, NE, KS, OK, TX, NM, AZ, CO, MT, UT, NV, WY:</i>				
Prairie dogs	Hand Baiting (treat from July to February)	not specified	1	yes
Ground squirrels	Aerial or Ground Broadcast (MT) Hand Baiting (MT, WY)	≤6	unlimited	yes
<i>Reforestation areas and/or Forest areas:</i>				
Voles White-footed mouse	Aerial or Ground Broadcast Trail Builder Hand Baiting	6-10 2-3 or ns 3-5 or ns	unlimited	no
Pocket gophers	Burrow Builder Hand Baiting	1-3 not specified	unlimited	no
<i>Noncrop Rights-of-way:</i>				
Ground squirrels	Hand Baiting	not specified	unlimited	yes
Voles	Aerial or Ground Broadcast	6-10	unlimited	yes
Voles	Ground Broadcast	≤6	1	yes
Ground squirrels	Ground Broadcast Hand Baiting (includes fruit and vegetable baits)	6	≥30-day int.	yes
Woodrats Kangaroo rats Ground squirrels Voles Cotton rat	Hand Baiting	not specified	unlimited	no
Commensal rats	Hand Baiting (CA)	not specified	every 3 mo.	yes
Pocket gophers	Burrow Builder Hand Baiting	1-3 not specified	unlimited	no

Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
<i>Sugarcane Fields:</i>				
Commensal rats Native rats	Aerial or Ground Broadcast	5	4	yes
<i>Noncrop areas:</i>				
Voles White-footed mouse	Ground Broadcast Trail Builder Hand Baiting	6-10 2-3 3-5	unlimited	yes
Woodchuck Marmot Black-tailed jackrabbit Kangaroo rats Ground squirrels Voles Moles	Hand baiting	not specified	unlimited	yes
Ground squirrels	Aerial or Ground Broadcast (MT)	≤6	unlimited	yes
Pocket gophers	Burrow Builder Hand Baiting	2-3 not specified	unlimited	no
<i>Sugar beets (CA):</i>				
Voles	Aerial or Ground Broadcast (aerial only for overwintered beets)	5-10	2 (30 day int.)	yes
<i>Macadamia Nut Orchards and Noncrop Sites Adjacent to Orchards (HI):</i>				
Commensal rats	Aerial or Ground Broadcast Bait Stations Burrow Treatment	5 not specified not specified	4	no

Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
<i>Pastures:</i>				
Voles White-footed mouse	Aerial or Ground Broadcast Trail Builder Hand Baiting	6-10 2-3 3-5	unlimited	no
Ground squirrels	Ground Broadcast Hand Baiting	6 not specified	≥30-day int.	yes
Woodchuck Marmot Black-tailed jackrabbit Woodrats Ground squirrels	Hand baiting	not specified	unlimited	yes
<i>Tree farms:</i>				
Woodrats Kangaroo rats	Hand Baiting	not specified	unlimited	no
<i>Nurseries, and/or Ornamentals, Highway medians, Plantings of nonbearing fruit trees, Conifer/Christmas trees:</i>				
Voles Ground squirrels	Hand Baiting	not specified	unlimited	yes
Voles	Ground Broadcast Hand Baiting	6-10 2-3	unlimited	no
Voles White-footed mouse	Aerial or Ground Broadcast Trail Builder Hand Baiting	6-10 2-3 3-5	unlimited	no
Ground squirrels	Ground Broadcast Hand Baiting	6 not specified	≥30-day int. unlimited	yes
Voles White-footed mouse	Ground Broadcast Trail Builder Hand Baiting	6-10 2-3 3-5	unlimited	yes
Commensal rats	Hand Baiting (CA)	not specified	every 3 mo.	yes

Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
Pocket gophers	Burrow Builder Hand Baiting	2-3 not specified	unlimited	no
Ground squirrels Voles Cotton rat Norway rat Roof rat	Hand Baiting	not specified	unlimited	yes
<i>Berry production (blueberry, blackberry, gooseberry, boysenberry, raspberry, strawberry):</i>				
Voles White-footed mouse	Ground Broadcast Trail Builder Hand baiting	6-10 3-4 3-5	unlimited	no
<i>Croplands:</i>				
Pocket gophers	Burrow Builder Hand Baiting	1-3 not specified	unlimited	no
Moles Pocket gophers	Hand Baiting	not specified	unlimited	no
Ground squirrels	Hand Baiting (MT)	≤6	unlimited	yes
<i>Corn Fields (no-till and minimum -tillage operations in OH):</i>				
Voles House mouse	Aerial or Ground Broadcast Planter Application	6-10 4-6	1-2 1	no
<i>Alfalfa and/or Timothy Hay Fields:</i>				
Meadow voles	Aerial or Ground Broadcast (after cuttings) (CA)	6-10	2 (30-day int.)	yes
Meadow vole	Bait Stations	not specified	unlimited	no
Pocket gophers	Burrow Builder Hand baiting	2-3 not specified	unlimited	no
Ground squirrels	Hand Baiting (MT)	≤6	unlimited	yes
<i>Uncultivated Agricultural Areas (CA):</i>				

Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
Voles	Aerial or Ground Broadcast	6-10	unlimited	yes
Commensal rats	Hand Baiting	not specified	unlimited	yes
<i>Waterways (streams, lakes, canals, ponds, bayous), Croplands, Turf:</i>				
Muskrat Nutria	Baiting on rafts (4' x 4' or 6" x 6")	not specified	≥30-day int.	yes
<i>Rights-of-way:</i>				
Voles White-footed mouse	Ground Broadcast Trail Builder Hand Baiting	3-10 2-3 3-5	unlimited	yes
Ground squirrels	Ground Broadcast Hand Baiting	6	≥30-day int.	yes
Ground squirrels Woodrats Voiles Cotton rat	Hand Baiting (CA)	not specified	unlimited	yes
Voiles (CA)	Aerial or Ground Broadcast	6-10	unlimited	yes
Commensal rats (CA)	Hand Baiting	not specified	every 3 mo. or not spec.	yes
<i>Along fence rows:</i>				
Ground squirrels	Ground Broadcast Hand Baiting	6 not specified	≥30-day int.	yes
<i>Crop rights-of-way and/or Noncrop borders :</i>				
Ground squirrels	Ground Broadcast Hand Baiting	6 not specified	≥30-day int.	yes
Voiles (CA)	Aerial or Ground Broadcast	6-10	unlimited	yes
Commensal rats (CA)	Hand Baiting	not specified	every 3 mo.	yes

Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
<i>Recreational Areas (e.g., campgrounds):</i>				
Voles (CA)	Aerial or Ground Broadcast	6-10	unlimited	yes
Commensal rats	Hand Baiting (late spring and summer)	not specified	unlimited	yes
<i>Areas inhabited by Cotton Rats and “Field Mice”:</i>				
Cotton rat Voles White-footed mouse	Ground Broadcast Hand Baiting	6-10 2-3	unlimited	no
<i>Rural Noncrop Sites Surrounding Residential and Resort Areas (HI):</i>				
Roof rat Polynesian rat House mouse	Aerial or Ground Broadcast	5	4	no
<i>Lawns, Golf Courses, Others (e.g., parks, turf and grass fields):</i>				
Moles Pocket gophers	Burrow Builder Hand Baiting	1-3 not specified	unlimited	no
Voles White-footed mouse	Ground Broadcast Trail Builder Hand Baiting	6-10 2-3 3-5	unlimited	yes
Ground squirrels	Ground Broadcast Hand Baiting (includes fruit and vegetable baits)	6 not specified	≥30-day int.	yes
Cotton rat Voles Ground squirrels	Hand Baiting (CA)	not specified	unlimited	yes

Use site/ Target spp.	Application methods (grain or pelleted bait unless otherwise specified)	Single appl. rate (lb bait/acre)	No. appl.	Pre- bait?
Grasses Grown for Seed (OR):				
Voles Deer mouse House mouse Ground squirrels	Ground Broadcast Hand Baiting (limitations exist on timing and extent of area that can be treated at any one time)	6-10 2-3	4 (per treated area)	no
<i>Cottonwood/Hybrid Poplar Plantations (OR) and Adjacent Noncrop Areas (WA):</i>				
Voles	Aerial or Ground Broadcast	5-10	unlimited	no
<i>Sugar Maple Orchards (VT):</i>				
Red squirrel Chipmunk Deer mouse	Bait Stations (November 1 to May 31 only)	1.5	7	yes

Target Species for Registered Uses of Zinc Phosphide

Rodents:

Commensal rats and mice:

Norway rat (*Rattus norvegicus*)

Roof rat (*R. rattus*)

House mouse (*Mus musculus*)

Ground squirrels:

Rock squirrel (*Spermophilus variegatus*)

Townsend's ground squirrel (*S. townsendii*)

California ground squirrel (*S. beecheyi*)

Columbian ground squirrel (*S. columbianus*)

Franklin's ground squirrel (*S. franklini*)

Golden-mantled ground squirrel (*S. lateralis*)

Richardson's ground squirrel (*S. richardsoni*)

Round-tailed ground squirrel (*S. tereticaudus*)

Thirteen-lined ground squirrel (*S. tridecemlineatus*)

Unita ground squirrel (*S. armatus*)

Belding's ground squirrel (*S. beldingi*)

Idaho ground squirrel (*S. brunneus*)

Wyoming ground squirrel (*S. elegans*)

Washington ground squirrel (*S. washingtoni*)

Antelope ground squirrel (*Ammospermophilus leucurus*)

Prairie dogs:

- White-tailed prairie dog (*Cynomys leucurus*)
- Black-tailed prairie dog (*C. ludovicianus*)
- Gunnison's prairie dog (*C. gunnisoni*)

Marmots:

- Yellow-bellied marmot (*Marmota flaviventris*)
- Woodchuck (*M. monax*)

Voles:

- Meadow vole (*Microtus pennsylvanicus*)
- Prairie vole (*M. ochrogaster*)
- Mountain vole (*M. montanus*)
- California vole (*M. californicus*)
- Pine vole (*M. pinetorum*)
- Townsend's vole (*M. townsendii*)
- Oregon vole (?)

Woodrats:

- Easter woodrat (*Neotoma floridana*)
- Southern plains woodrat (*N. micropus*)
- Whitethroat woodrat (*N. albigula*)
- Desert woodrat (*N. lepida*)
- Mexican woodrat (*N. mexicana*)
- Dusky-footed woodrat (*N. fuscipes*)
- Bushytail woodrat (*N. cinerea*)

Kangaroo rats:

- Ord's kangaroo rat (*Dipodomys ordii*)
- Merriam's kangaroo rat (*D. merriami*)
- Banner-tailed kangaroo rat (*D. spectabilis*)

Pocket gophers:

- Botta's pocket gopher (*Thomomys bottae*)
- Camas pocket gopher (*T. bulbivorus*)
- Wyoming pocket gopher (*T. clusius*)
- Idaho pocket gopher (*T. idahoensis*)
- Mountain pocket gopher (*T. monticola*)
- Northern pocket gopher (*T. talpoides*)
- Townsend's pocket gopher (*T. townsendii*)
- Southern pocket gopher (*T. umbrinus*)
- Desert pocket gopher (*Geomys arenarius*)
- Plains pocket gopher (*G. bursarius*)
- Texas pocket gopher (*G. personatus*)
- Southeastern pocket gopher (*G. pinetis*)
- Yellow-faced pocket gopher (*Pappogeomys castanops*)

Native mice and rats:

- White-footed mouse (*Peromyscus leucopus*)
- Deer mouse (*P. maniculatus*)

Oldfield mouse (*P. polionotus*)
Jumping mice (*Zapus spp.*)
Cotton rat (*Sigmodon hispidus*)
Rice rat (*Oryzomys palustris*)
Florida water rat (*Neofiber alleni*)

Others:

Polynesian rat (*Rattus exulans*)
Muskrat (*Ondatra zibethicus*)
Nutria (*Myocastor coypus*)
Red squirrel (*Tamiasciurus hudsonicus*)
Eastern chipmunk (*Tamias striatus*)

Lagomorphs:

Black-tailed jackrabbit (*Lepus californicus*)

Insectivores:

Eastern mole (*Scalopus aquaticus*)
Broad-footed mole (*Scapanus latimanus*)
Coast mole (*S. orarius*)
Townsend's mole (*S. townsendii*)
Star-nosed mole (*Condylura cristata*)